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OIPE JC17
JUL 28 2004
PATENT & TRADEMARK OFFICE

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1617

Re: U.S. Utility Patent Application
Application No. 10/824,357; Filed: April 15, 2004
For: **Methods of Treating Pain and Compositions for Use Therefor**
Inventor: Najib BABUL
Our Ref: 2039.0010001

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement (**2** pp.);
2. Form PTO-1449 listing **38** cited documents (**9** pp.);
3. Copies of **25** cited documents; and
4. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Matthew J. Dowd

Matthew J. Dowd
Agent for Applicant
Registration No. 47,534

MJD/rjv
Enclosures
292649_1.DOC

OIPE JC17
JUL 28 2004
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
Najib BABUL
Appl. No.: 10/824,357
Filed: April 15, 2004
For: **Methods of Treating Pain and Compositions for Use Therefor**

Confirmation No.: 6312
Art Unit: 1617
Examiner: *To Be Assigned*
Atty. Docket: 2039.0010001

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents AA1-AK1, AA2, and AB2 are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003." A copy of each remaining document is provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Matthew J. Dowd
Agent for Applicant
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Date: July 28, 2004

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 2039.0010001	APPLICATION NO. 10/824,357
	APPLICANT Najib BABUL	
	FILING DATE April 15, 2004	GROUP 1617

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,486,436	12/04/1984	Sunshine *et al.*			03/11/1983
	AB1	4,567,183	01/28/1986	Sunshine *et al.*			12/12/1983
	AC1	4,777,174	10/11/1988	Sunshine *et al.*			03/02/1987
	AD1	4,965,065	10/23/1990	Lukacsko *et al.*			02/06/1987
	AE1	5,043,358	08/27/1991	Lukacsko *et al.*			09/04/1990
	AF1	5,071,842	12/10/1991	Lukacsko *et al.*			12/21/1989
	AG1	5,321,012	06/14/1994	Mayer *et al.*			04/06/1993
	AH1	5,767,125	06/16/1998	Crain *et al.*			12/03/1996
	AI1	6,007,841	12/28/1999	Caruso, F.S.			03/13/1998
	AJ1	6,054,451	04/25/2000	Caruso, F.S.			04/21/1998
	AK1	6,117,871	09/12/2000	Maurer *et al.*			11/25/1996

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Aronoff, G.M., and Gallagher, R.M., "Chapter 32. Pharmacological Management of Chronic Pain: A Review," in *Evaluation and Treatment of Chronic Pain, 3rd edition*, Mitchell, C.W., ed., pp. 433-453, Williams & Wilkins, Baltimore, MD (1999).
	AS	1	Beaver, W.T., "Chapter 33. Nonsteroidal Anti-Inflammatory Analgesics and Their Combinations with Opioids," in *Evaluation and Treatment of Chronic Pain, 3rd edition*, Mitchell, C.W., ed., pp. 455-473, Williams & Wilkins, Baltimore, MD (1999).
	AT	1	Cherny, N.I., and Portenoy, R.K., "Chapter 66. Practical issues in the management of cancer pain," in *Textbook of Pain, 4th edition*, Wall, P.D., and Melzack, R., eds., pp. 1479-1522, Harcourt Publishers Limited, London, England (1999).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	6,160,020	12/12/2000	Ohannesian *et al.*			06/19/1998
	AB2	6,187,338 B1	02/13/2001	Caruso *et al.*			02/22/1999
	AC						
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Grass, S., *et al.*, "*N*-methyl-D-aspartate receptor antagonists potentiate morphine's antinociceptive effect in the rat," *Acta Physiol. Scand. 158*:269-273, Scandinavian Physiological Society (1996).
	AS	2	Jackson, L.M., and Hawkey, C.J., "COX-2 Selective Nonsteroidal Anti-Inflammatory Drugs: Do They Really Offer Any Advantages?" *Drugs 59*:1207-1216, Adis International Limited (2000).
	AT	2	Kamali, F., "Rofecoxib Merck & Co Inc," *Current Opinion in CPNS Investigational Drugs 1*:126-131, Current Drugs Ltd (1999).

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	3	Katz, N.P., "MorphiDex® (MS:DM) Double-Blind, Multiple-Dose Studies in Chronic Pain Patients," *J. Pain Symptom Manage. 19 (Suppl.)*:S37-S41, Elsevier (2000).
	AS	3	Kauppila, T., *et al.*, "Dextromethorphan potentiates the effect of morphine in rats with peripheral neuropathy," *Neuroreport 9*:1071-1074, Rapid Science Ltd (1998).
	AT	3	Laudanno, O.M., *et al.*, "Gastrointestinal Damage Induced by Celecoxib and Rofecoxib in Rats," *Dig. Dis. Sci. 46*:779-784, Plenum Publishing Corporation (2001).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Mao, J., *et al.*, "Oral administration of dextromethorphan prevents the development of morphine tolerance and dependence in rats," *Pain* 67:361-368, International Association for the Study of Pain (1996).
	AS	4	Pasternak, G.W., and Letchworth, S.R., "Future opioid analgesics: Targeting the old and the new," *Current Opinion in CPNS Investigational Drugs* 1:54-64, Current Drugs Ltd (1999).
	AT	4	Sunshine, A., "Chapter 38. Profile of NSAID + Opioid Combination Analgesics," in *Pain: Current Understanding, Emerging Therapies, and Novel Approaches to Drug Discovery*, Bountra, C., *et al.*, eds., Marcel Dekker, Inc., New York, NY (May 2003).

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	5	Twycross, R.G., "Chapter 51. Opioids," in *Textbook of Pain, 4th edition*, Wall, P.D., and Melzack, R., eds., pp. 1187-1214, Harcourt Publishers Limited, London, England (1999).
	AS	5	Wallace, J., and Chin, B., "Celecoxib GD Searle & Co," *Current Opinion in CPNS Investigational Drugs* 1:132-141, Current Drugs Ltd (1999).
	AT	5	Hughes, C.E., *et al.*, "Discriminative-Stimulus Effects of Morphine in Combination With α- and ß-Noradrenergic Agonists and Antagonists in Rats," *Pharmacol. Biochem. Behav.* 53:979-986, Elsevier Science Inc. (1996).

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	6	Szczeklik, A., *et al.*, "Salmeterol Prevents Aspirin-induced Attacks of Asthma and Interferes with Eicosanoid Metabolism," *Am. J. Respir. Crit. Care Med. 158*:1168-1172, American Lung Association (1998).
	AS	6	Bentley, G.A., and Starr, J., "The antinociceptive action of some ß-adrenoreceptor agonists in mice," *Br. J. Pharmacol. 88*:515-521, The Macmillan Press Ltd. (1986).
	AT	6	Brochet, D., *et al.*, "Antinociceptive activity of beta-adrenoceptor agonists in the hot plate test in mice," *Psychopharmacology 88*:527-528, Springer-Verlag (1986).

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	AR	7	Grubb, M.N., and Burks, T.F., "Selective Antagonism of the Intestinal Stimulatory Effects of Morphine by Isoproterenol, Prostaglandin E_1 and Theophylline," *J. Pharmacol. Exp. Ther.* *193*:884-891, The Williams & Wilkins Co. (1975).
	AS	7	Kindman, L.A., *et al.*, "Opioids Potentiate Contractile Response of Rabbit Myocardium to the Beta Adrenergic Agonist Isoproterenol," *J. Cardiovasc. Pharmacol.* *17*:61-67, Raven Press, Ltd. (1991).
	AT	7	Koster, A.S., *et al.*, "Glucuronidation of Morphine and Six β_2-Sympathomimetics in Isolated Rat Intestinal Epithelial Cells," *Drug Metab. Dispos.* *13*:232-238, The American Society for Pharmacology and Experimental Therapeutics (1985).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Osada, E., *et al.*, "Pharmacological Studies of Mabuterol, a New Selective ß$_2$-Stimulant. III: Effects on the central nervous system, striated muscle and carbohydrate and lipid metabolism," *Arzneimittelforschung 34*:1652-1658, Editio Cantor (1984).
	AS	8	Rees, M.R., *et al.*, "The Effect of ß-Adrenoreceptor Agonists and Antagonists on Gastric Emptying in Man," *Br. J. Clin. Pharmacol. 10*:551-554, Macmillan Publishers Ltd. (1980).
	AT	8	Silvasti, M., *et al.*, "Pharmacokinetic comparison of a dextromethorphan-salbutamol combination tablet and a plain dextromethorphan tablet," *Int. J. Clin. Pharmacol. Ther. Toxicol. 28*:268-272, Dustri-Verlag Feistle (1990).

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Yabuuchi, K., *et al.*, "Intracerebroventricular injection of isoproterenol produces its analgesic effect through interleukin-1 ß production," *Eur. J. Pharmacol.* 334:133-140, Elsevier Science B.V. (1997).
	AS		
	AT		

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